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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,561	03/27/2001	Larry L. Hood	155694-0054	2600

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IRELL & MANELLA LLP
840 NEWPORT CENTER DRIVE
SUITE 400
NEWPORT BEACH, CA 92660

EXAMINER

SHAY, DAVID M

ART UNIT	PAPER NUMBER
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3735

DATE MAILED: 06/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/819,561

Applicant(s)

HOOD

Examiner

david shay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 13, 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 and 36-59 is/are pending in the application.
- 4a) Of the above claim(s) 5-34, 39, 48, 49, 52 and 55-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 36-38, 40-47, 50, 51, 53 and 54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 13, 2006 has been entered.

It is noted at the outset that applicant's response is not in conformance with 37 CFR 121(c)(5), in that the status identifiers for the withdrawn claims are not correct. However, as the response does appear to be a bona fide response, the amendment will be acted on. Applicant is required to use the proper status identifiers in subsequent responses.

Applicant argues that the laser of Bille et al "clearly discusses either ablating or liquefying the tissue", and thus cannot teach the claimed invention wither alone or in combination with any of the secondary references. The examiner must respectfully disagree. In fact Bille et al teaches that the laser energy discussed therein changes the tissue into a "semi-liquid" state, this occurs when the laser is applied at a realatively low power density "where mostly water is evaporated and relatively few molecular bonds are being broken, the tissue is modified and softened" (see column 7, lines 33-39). Clearly the tissue is not liquefied, merely softened.

With regard to the Spears et al reference, applicant argues the "Spears does not disclose creating a column of denatured tissue that has an essentially uniform cross-sectional area of at least a portion of a stroma" as claimed. While the examiner does concede that Spears et al does not state this *ipsis verbis*, it is clear that the device of Figure 5 will produce such a denatured area, since the laser beam applied is collimated. As applicant has set forth no possible

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mechanism, parameters, or theory which would explain how the disclosed device would produce a column of denatured tissue that was of more uniform area than the column that would be produced by the device of Figure 5 of Spears et al, this argument is not convincing.

The amendment filed March 22, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "without ... liquefying corneal tissue".

Applicant is required to cancel the new matter in the reply to this Office Action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 36-38, 40-47, 50, 51, 53, and 54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure is silent with respect to "without ... liquefying corneal tissue"

Claims 1, 2, 45-47, 51, 53 and 54 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bille et al.

Claims 1-3, 36-38, 40, 42, 45-47, 51, 53 and 54 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Spears et al.

Claims 1-4 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bille et al in combination with Knopp et al. Bille et al teaches denaturing tissue. Knopp et al disclose a medical system that can denature a cornea comprising laser (item 87), a stepper motor (item 41), and a lens (items 17 and 23). It would have been obvious to employ the laser of Bille et al in the device of Knopp et al, since this provides recurvature without affecting surface tissue, as taught by Bille et al or to employ the focal point displacement mechanism of Knopp et al, since Bille et al provides no particulars of the mechanisms for moving the beam, thus producing a device such as claimed.

Claims 36-38 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bille et al in combination with Klopotek. Bille et al teaches denaturing eye tissue. Klopotek teaches configuring the intensity of an incident laser beam. It would have been obvious to the artisan of ordinary skill to employ the laser of Bille et al in the device of Klopotek, since this provides a non destructive recurvature or to employ the intensity configuring mask of Klopotek in the device of Bille et al, since it will work equally well with any laser, thus producing a device such as claimed.

Claims 1, 40, 41, 45 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knopp et al in combination with Bille et al, as applied to claims 1-4 and 40 are above, and further in view of L'Esperance Jr. L'Esperance Jr. teaches an ocular surgery device which provides for the movement of the beam focal point in a circular pattern about the cornea at a predetermined diameter. It would have been obvious to the artisan of ordinary skill to employ a

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scanner with a scan pattern as taught by L'Esperance, Jr., since this is a useful pattern for ophthalmic surgery and to produce the pattern with the diameter of 6-8 millimeters, since L'Esperance, Jr. says only that the distance needs to be "predetermined" and using a distance of 6-8 millimeters would place it outside of the optically used portion of the cornea, which will prevent visual distortions as is notorious in the art, thus producing a device such as claimed.

Claims 1, 40, 41, 45 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knopp et al in combination with Bille et al, as applied to claims 1-4 and 40 are above, and further in view of L'Esperance Jr. L'Esperance Jr. teaches an ocular surgery device which provides for the movement of the beam focal point in a circular pattern about the cornea at a predetermined diameter. It would have been obvious to the artisan of ordinary skill to employ a scanner with a scan pattern as taught by L'Esperance, Jr., since this is a useful pattern for ophthalmic surgery and to produce the pattern with the diameter of 6-8 millimeters, since L'Esperance, Jr. says only that the distance needs to be "predetermined" and using a distance of 6-8 millimeters would place it outside of the optically used portion of the cornea, which will prevent visual distortions as is notorious in the art, thus producing a device such as claimed.

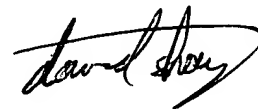
Claims 37 and 42-44 are rejected under 35 U.S.C 103(a) as being unpatentable over Bille et al in combination with Klopotek as applied to claims 36-38 and 42 above, and further in view of L'Esperance, Jr. L'Esperance, Jr. teaches providing a circularly scanned spot, which denatures tissue. Thus it would have been obvious to the artisan of ordinary skill to employ the intensity modifier of Klopotek to produce the intensity pattern of the spot in the method of L'Esperance, Jr. since the outputs of laser such as used by L'Esperance, Jr. have a non-uniform intensity distribution, thus producing a method such as claimed.

Applicant's arguments filed October 5, 2005 have been fully considered but they are not persuasive. The arguments are not convincing for the reasons set forth above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330